SECOND INSTALLMENT

Clinical Trial Data Transparency Forum

SAS World Headquarters
Cary, NC
February 11, 2014

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The Forum is being webcast live to a pre-determined registered audience and recorded for OnDemand availability.

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Welcome, Introduction and Goals

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Agenda

9:00 am	**Welcome, Introductions and Goals** ***Matt Gross***, *Director, Health and Life Sciences Global Practice,* ***SAS***
9:15 am	**Update on the Regulatory Landscape** ***Benjamin Rotz***, *Advisor, Medical Transparency,* ***Eli Lilly***
10:00 am	**Best Practices for Building a Front-end System** ***Scott Shaunessy***, *Chief Executive Officer,* ***ideaPoint***
10:30 am	**Solution Development Status for Single and Multi-sponsor Platforms** ***Matt Gross***, *Director and* ***Bill Gibson***, *Portfolio Manager, Health and Life Sciences Global Practice,* ***SAS***
11:15 am	**Lunch**

Agenda

12:15 pm	**Lessons Learned from Current Implementations** • ***Andrew Freeman***, *Head of Medical Policy and* ***Peter McMeekin***, *Director, R&D IT,* ***GlaxoSmithKline*** • ***Rebecca Sudlow***, *Associate Director Biostatistics and* ***Martin Sauer***, *Lead Business Solution Manager,* ***Roche*** • ***Andy Lawton***, *Global Head of Clinical Data Management,* ***Boehringer Ingelheim***
1:45 pm	**Breakout Discussion Groups** • **De-identification and protection of participants:** *Preventing a researcher from identifying actual individuals from the available data* • **Independent review panel:** *Determining how the review panel, established to assess research proposals, should operate* • **Multi-sponsor platform:** *Enabling a researcher to access data from multiple sponsors via a single analytics platform*
2:45 pm	**Summary of Breakout Discussion Groups**
3:15 pm	**Critical Components to Move Forward and Next Steps**
3:30 pm	**Networking Reception**

Introductions

- **Facilitator**
  - **Matt Gross**
- **Logistics and support**
  - **Becky de Tenley**
  - **Sharon Hia**
- **SAS Solution**
  - **Delivery**
    - **Angela Lightfoot**
  - **Product**
    - **Bill Gibson**

Goals and Objectives

- **Discuss**
  - **What is clinical trial data transparency**
  - **What is the industry's perspective**
  - **Understand what is being offered**
  - **Hear what others are doing/have done**
- **Debate**
  - **Different approaches to meeting requirements**
  - **Different perspectives on what is needed**
- **Decide**
  - **What can be agreed on**
  - **What needs further discussion or industry guidance**
  - **How to gain consensus and agreement**

Who is here

- **People**
  - **70 registered on-site**
  - **Several dozens viewing live broadcast**
- **Companies**
  - **28 different companies**
- **Enablers**
  - **Companies delivering tools and solutions enabling Clinical Trial Data Transparency**
- **Doers**
  - **Seven companies that are actively engaged with the development and delivery of a clinical trial data transparency environment**

Solution Overview

Public access site

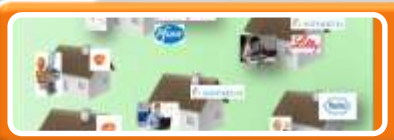
- Researcher request process
- New data inquiries

Independent Review Panel and Process

- Panel
- Notification

The Researcher Access Solution

- Secure storage and access of data
- A collaborative, analytic environment
- Easily accessible from anywhere with all tools included



Multi-Sponsor Environment

- Playing nicely with your peers

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Solution Development Status
Single and Multi-Sponsor Environments

Matt Gross – Director
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Bill Gibson – Portfolio Manager
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Agenda

- Solution Overview
- Single Instance vs. Multi Sponsor Environment
- Packaging approach
- Product Roadmap
- Product Input
- Walkthrough
- Q&A

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Solution Overview
Researcher Access Site

- Sponsor Perspective
  - **Storage for Clinical Trial Data**
    - **Granular permissions for controlled access**
  - **Researcher setup**
    - **User Management**
    - **Researcher Group setup**
  - **Support for Third-Party Apps**
  - **Import / Export Controlled Information Process**
  - **User Education**
  - **User Technical Support**
  - **Hosting , Maintenance and Administration**

Solution Overview
Researcher Access Site

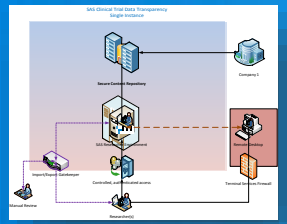
- Researcher Perspective
  - **Web-access anywhere to research environment**
  - **Research Project Environment**
    - **Organization and storage of files**
  - **Read-only access to approved sponsor's data**
  - **Ability to create, run and save analyses**
    - **SAS, "R"**
    - **Additional Third-Party Apps (If provided by sponsor)**
      - **e.g. OpenOffice, R Studio, Microsoft Office, et.c**
  - **Collaboration tools**
  - **Import and export process to request information into and out of system**
  - **User Guides and Videos**
  - **Technical Support Access**

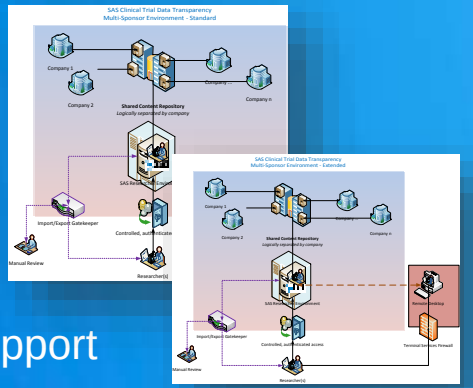
Solution Overview
Researcher Access Site

- **Hosting Perspective**
  - **Always available except for scheduled downtimes**
  - **Backups of system**
  - **Updates to environment**
  - **Updates to solution**
  - **24x7 access to technical support for Researchers**
  - **Scalable Platform**
    - **Storage, Researcher Projects, Analysis Environment**
  - **Support/Project Management for Customers**

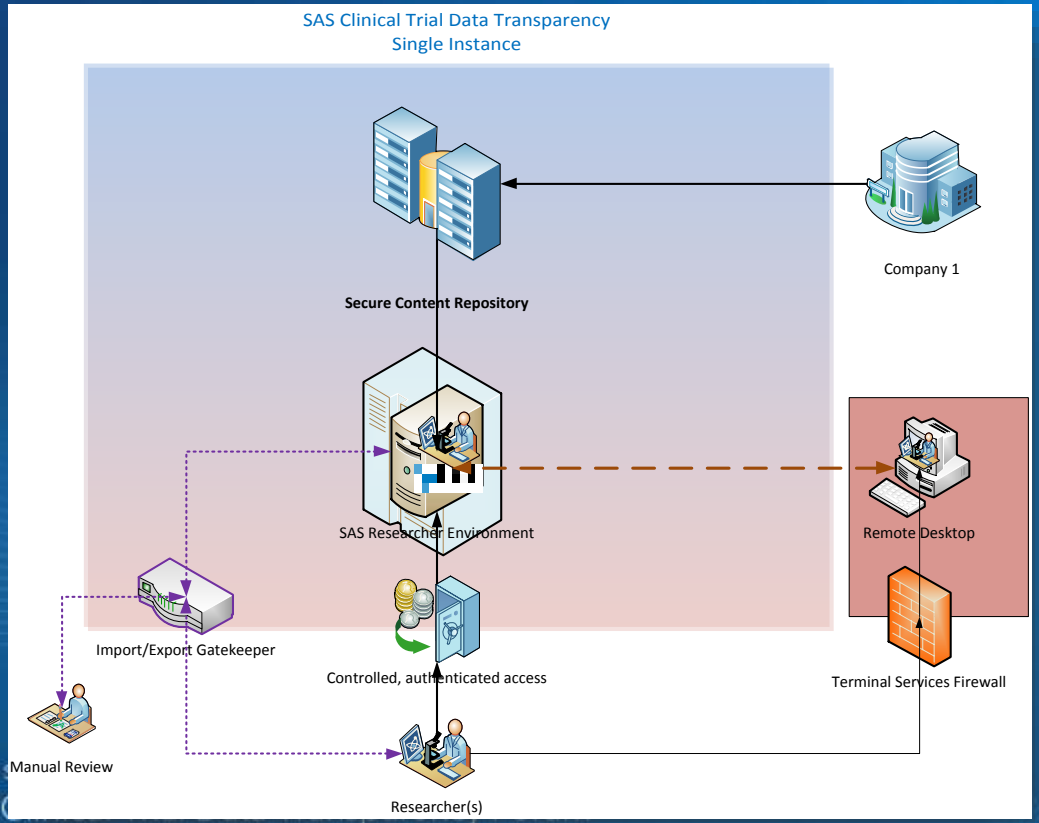
Single Instance vs. Multi-Sponsor Environment

- Single Instance
  - Individual company owns the instance
  - Physically separated hardware and data storage
  - User-based model
- Multi-Sponsor Environment
  - Shared environment
  - Logically segregated sponsor data
  - Researcher access to multiple sponsors' information
  - Research Project-based model
  - Supports requests for multiple sponsors' data
  - Distributed costs for hosting, hardware, administration and support
  - Supports low-entry cost for non-profits and regulatory entities



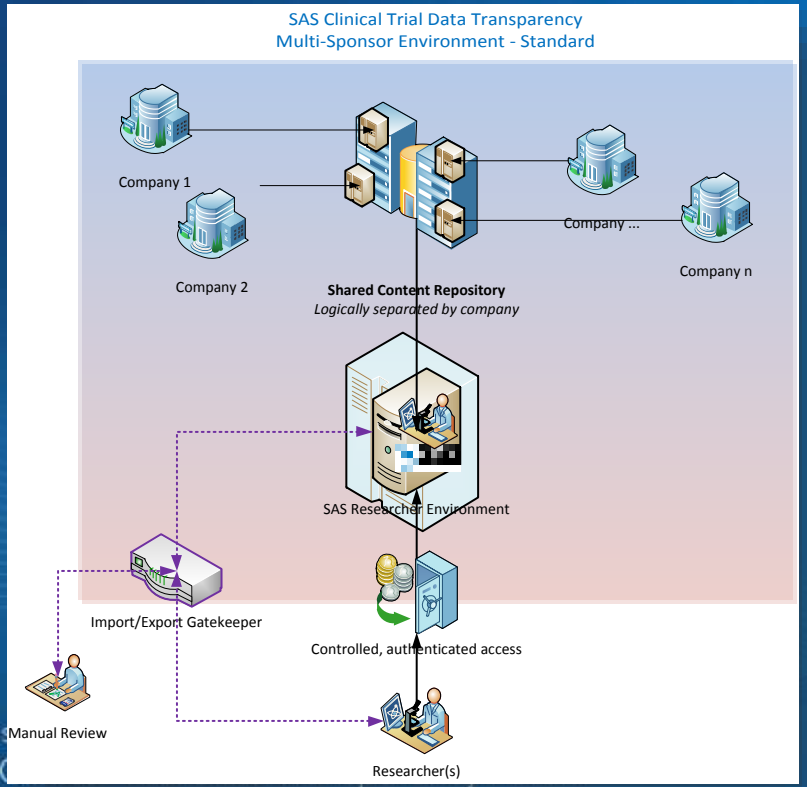


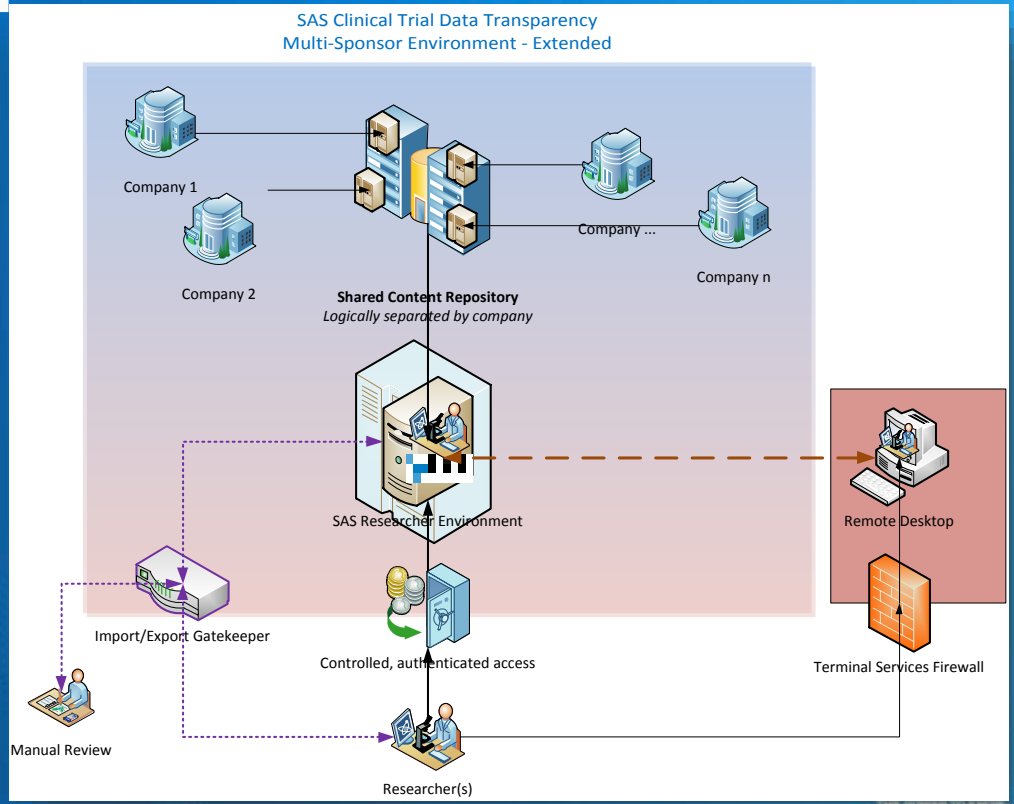
Single Instance



- Tiered Pricing Model based on Company Size (revenue)
  - Large, Medium or Small
  - Not applicable for Non-Profit or Regulatory
- Single Instance
  - Own whole solution
  - Researcher-based pricing (not by research project)
  - Includes “Extended” environment for third-party apps
- Buy-in for environment, initial block of users and initial storage
- Includes hosting, tech support, administration, initial implementation and user education (guide, videos, help, etc.)
- Ability to scale up as needed

Multi-Sponsor Environment - Comparisons





CTDT Packaging Overview Multi-Sponsor Environment

- Tiered Pricing Model based on Company Size (revenue)
  - Large, Medium, Small and Non-profit/regulatory
- Single solution focused on supporting a large number of research projects
- Project-based pricing (not by number of researchers or which sponsors' data)
- Baseline support for analysis and access (No third-party apps)
- Buy-in for environment, initial block of projects and initial storage
- Includes hosting, tech support, administration, initial implementation and user education (guide, videos, help, etc.)
- Ability to scale up as needed but distributed across all companies based on size
- MSE Extended
  - Provides environment for third-party apps

MSE THE PLANNED COMMUNITY ANALOGY

- Rather than paying for user licenses…
  - Each company's membership supports a set number of "houses" for research projects
  - Large Pharmas add 100 "houses", medium Pharmas add 50 "houses", small add 20

The Clinical Trial Data Transparency Community

The "MSE"

MSE

THE PLANNED COMMUNITY ANALOGY
AN HOA APPROACH

- Each researcher uses one “house” for each research project
  - Doesn’t matter how many companies’ data is accessed
  - A researcher could use multiple “houses” if they have multiple approved research projects

THE PLANNED COMMUNITY ANALOGY
AN HOA APPROACH

- SAS keeps track of when the MSE is close to full occupancy
  - Each company is then asked to contribute an additional amount to enlarge the community for the needed growth
  - Approaches in place to handle skewed usage

CTDT Product

- **Roadmap**
  - **CTDT 4.4 and MSE – Now**
    - **Secure Viewers**
    - **Direct R submission through Researcher Environment**
  - **CTDT 4.5**
    - **Direct access to remote desktop**
- **Market Input**
  - **Roundtables**
  - **CTDT Advisory Panel**
- **User Feedback**
  - **Usability Testing**

Walkthrough and Q&A

- **What do you want to know about solution?**
- **What is missing?**
- **Where does this need to go?**